REMARKS

Objection to Claims 60, 61, 63, 84 and 85 under 37 CFR 1.75(c)

Claims 60, 61, 63, 84 and 85 are objected to as being in improper form as a multiple dependent claim should refer to other claims in the alternative only. Applicant has amended the claims such that they refer to other claims in the alternative. The objection may be withdrawn.

Objection to Claim 83 under 37 CFR 1.75

Claim 83 is objected to as being a duplicate of Claim 80. As both Claims 80 and 83 have been allowed, Applicant hereby cancels Claim 83 without prejudice. The objection may be withdrawn.

Rejection of Claims 56-76, 81, 82, 84 and 85 under 35 U.S.C. 112, second paragraph (indefiniteness)

Claims 56-59, 69, 72, 74-76 and 81-82 and claims dependent thereon are rejected as being indefinite as they allegedly recite an arbitrary protein name, CRP1. While Applicant contends that one skilled in the art would clearly understand the meaning of the term "CRP1" in light of the teachings of the specification, Applicant has amended the claims to recite CRP1 "of Figure 13A (SEQ ID NO:22)". These amendments are made solely to advance prosecution and without acquiescing to the rejection. The rejection may be withdrawn.

Claims 56 and 57 are rejected as indefinite as there is allegedly insufficient antecedent basis for the recitation of "a nucleotide sequence". Applicant has amended the claims to recite "comprising a nucleotide sequence" in the preamble, thereby obviating the rejection.

Claim 85 is rejected as being incomplete for allegedly omitting essential process steps. The Examiner has cited MPEP 2172.01 which states, in part, that " ... a claim which fails to interrelate essential elements of the invention as defined by the applicant(s) in the specification may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention." Applicant contends that the essential element of Claim 85 is the expression of a nucleic acid molecule comprising the recited nucleotide sequences and that such an element is, in and of itself, sufficient to obtain the claimed polypeptide. No additional process steps would be required in the claim as they are not essential to obtaining the claimed polypeptide. Moreover, the claim as it stands points out and distinctly claims the invention. In view of the above remarks, the rejection may be withdrawn.

Rejection of Claims 56-64, 67-69, 72-74, 82, 84 and 85 under 35 U.S.C. 112, first paragraph (written description)

Claim 61 is rejected, as there is allegedly insufficient written description in the specification for the term "derivative". The Examiner alleges that the record is not clear as to whether the term "derivative" is limited to a chemical modification or if it also encompasses amino acid sequence variation.

The term "derivative" is clearly defined in the specification at p. 43, lines 1-11, which reads in part as follows:

> As used herein, the term "CRP1 or B7RP1 polypeptide derivatives" refers to CRP1 or B7RP1 polypeptides, variants, or fragments thereof, that have been chemically modified, as for example, by addition of one or more water soluble polymers, N-linked or O-linked carbohydrates, sugars, phosphates, and/or other such molecules, where the molecule or molecules are not naturally attached to wild-type CRP1 or B7RP1 polypeptides ... .

Based on the disclosure, a derivative encompasses a chemical modification, although the chemical modification may include a change in the amino acid sequence of CRP1 or B7RP1 in order to introduce the modification, as in the case of addition of a new N-linked or O-linked carbohydrate chain. Applicant contends that the specification provides written description for a polypeptide "derivative".

Claims 68, 73 and 82 are rejected as there is allegedly insufficient written description in the specification for the recitation of "comprising an amino acid sequence that is at least 95 percent identical. Although Applicant's amendment of 8/9/04 was deemed to overcome the previous rejection of the claims on the basis that they lacked any recitation of a testable functional activity, the rejection was nonetheless maintained for the reasons of record. It appears that the Examiner continues to reject these claims allegedly because there is no indication of a structural basis in the B7RP1 polypeptide, which must be maintained by the members of the genus in order to have the recited functional activity. Applicants disagree.

Applicant has disclosed the amino acid sequences of both murine and human B7RP1 and compared the two sequences in Figure 12B. Also shown in the figure is a "consensus" sequence, which identifies amino acid residues, shared by both murine and human B7RP1. The specification clearly shows conserved amino acid residues, which are implicated in the structure and function of a B7RP1 polypeptide and therefore must be maintained in order to have activity. It should be noted that murine B7RP1 is 43% identical human B7RP1 at the amino acid sequence level, whereas the claims

recite polypeptides which are 95% identity to human B7RP1. In addition, it is disclosed that the extracellular domain of B7RP1 comprises two Ig loops formed by conserved cysteine residues, which is another structural basis for activity (see p. 23, lines 25-28 of the specification). In view of the above, Applicant contends that polypeptides comprising an amino acid sequence that is at least 95% identical are sufficiently described in the specification.

Claims 57-59, 67, 69, 72 and 74 are rejected as the recitation of "comprising a fragment" was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner argues that there must be a conserved structure that is representative of the claimed genus. The Examiner also states that comprising language is appropriate to polypeptides comprising an internal fragment to which a particular function can be attributed.

Without acquiescing to the rejection and solely to advance prosecution, Applicant has amended the claims as follows. Claims 56(e), 57(e), 58(c), 59(c), 69 and 74 have been amended such that they no longer recite "comprising" in connection with nucleic acid or polypeptide fragments. Claims 67 and 72 have been amended to recite a fragment which comprises "an extracellular domain". An extracellular domain of B7RP1 is characterized by having a particular function, such as binding to CRP1 (see Example 21). The rejection may be withdrawn.

Claims 57, 59-64, 70, 72-74, 79, 81, 82, 84 and 85 are rejected as the recitation of "GenBank Accession No. AB014553" does not fulfill the written description requirement. The Examiner argues that the amino acid sequence disclosed in the GenBank entry is required for making and using the claimed invention and, as essential subject matter, should be introduced by amendment into the specification.

Applicant acknowledges the invitation by the Examiner to amend the specification to include the amino acid sequence of Gen Bank Accession No. AB014553 and respectfully requests that consideration of such an amendment be deferred until such time as all other outstanding rejections against the claims have been withdrawn.

Rejection of Claims 56-76, 81, 82, 84 and 85 under 35 U.S.C. 112, first paragraph (enablement)

Claims 56-76, 81, 82, 84 and 85 are rejected as the specification allegedly does not enable "a polypeptide that has an activity of binding to CRP1" where CRP1 is defined as in the last paragraph of p. 41 of the specification. While Applicant contends that the teachings of the specification clearly enable one to make and use a polyeptide having an activity of binding CRP1, Applicant has amended

the claims to recite CRP1 "of Figure 13A (SEQ ID NO:22)". These amendments are made solely to advance prosecution and without acquiescing to the rejection. The rejection may be withdrawn.

Rejection of Claims 56-64, 67-69, 72-74, 82, 84 and 85 under 35 U.S.C. 112, first paragraph (enablement)

Claim 61 is rejected, as the specification allegedly does not enable a polypeptide "derivative". The Examiner has not set forth any reasons why the presently claimed polypeptide derivatives are not enabled and, in particular, why the teachings of the specification at p. 48, line 6 to p. 50, line 21 as well as those in the art with respect to making and using polypeptide derivatives would not enable the claimed invention. Nonetheless, without acquiescing to the rejection and solely to advance prosecution, Applicant has amended Claim 61 to clarify that the polypeptide derivatives are "modified with one or more chemical groups." The rejection may be withdrawn.

Claims 68, 73 and 82 are rejected as the specification allegedly does not enable a polypeptide "comprising an amino acid sequence that is at least 95 percent identical" even if a testable function is stated, for the reasons made of record. In the Office Action of August 9, 2004, the Examiner suggested that Applicant consider a claim to a limited variation (e.g., 95% identity) over the full length of the sequence and possessing a testable functional activity. In the present action, however, such a claim is still deemed unacceptable, apparently because of Applicant's use of the term "comprising". The Examiner has not set forth any reasons why the use of the term "comprising" establishes a case of non-enablement. Claims 68 and 73, for example, still recite a polypeptide which is at least about 95% identical to SEQ ID NO:6 or SEQ ID NO:12 and have a testable functional activity, and there is no basis to conclude that the presence of amino acid sequences flanking those in SEQ ID NO:6 or SEQ ID NO:12 (as suggested by the term "comprising") would cause undue experimentation in the practice of the claimed invention. Applicant requests withdrawal of the rejection.

Claims 57-59, 67, 69, 72 and 74 are rejected as the specification allegedly does not enable a polypeptide "comprising a fragment" of a reference sequence unless a particular function can be attributed to a specific fragment. Without acquiescing to the rejection and solely to advance prosecution, Applicant has amended the claims as follows. Claims 56(e), 57(e), 58(c), 59(c), 69 and 74 have been amended such that they no longer recite "comprising" in connection with nucleic acid or polypeptide fragments. Claims 67 and 72 have been amended to recite a fragment, which comprises "an extracellular domain". An extracellular domain of B7RP1 is characterized by having a particular function, such as binding to CRP1 (see Example 21). It is maintained that the specification clearly

enables an extracellular domain or a portion thereof having the recited activities and undue experimentation would not be required to identify and test related polypeptides for binding to CRP1 or stimulating T cell proliferation and/or activation. The rejection may be withdrawn.

CONCLUSION

Claims 56-85 are in condition for allowance and an early notice thereof is solicited.

Respectfully submitted,

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